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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,526	04/08/2004	Harvey A. Schwertner	AFD 490A	4313

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT PAPER NUMBER

1743

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/828,526	Applicant(s) SCHWERTNER, HARVEY A.	
	Examiner Maureen M. Wallenhorst	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 and 4 is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1743

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: It does not claim priority to application serial no. 10/016,826 under 35 USC 120.

2. Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite since it is not clear what the threshold level of serum total bilirubin represents in the method. Does this level represent the maximum or minimum allowed level of serum total bilirubin in a normal individual without systemic lupus erythematosus? In addition, it is not clear whether the individual's serum total bilirubin level has to be higher or lower than the threshold level to be diagnosed with systemic lupus erythematosus. See these same problems in claim 3 with regards to characterizing the risk of psoriatic arthritis in an individual.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1743

2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwertner (US Patent no. 5,380,667) in view of Manzi et al.

Schwertner teaches of a method for determining the risk of coronary artery disease in an individual by measuring the level of the individual's serum total bilirubin, comparing the measured level to a threshold level for serum total bilirubin, and determining from the comparison the likelihood that the individual is at an increased risk for severe coronary artery disease, wherein levels below the threshold level of serum total bilirubin indicates that the individual is at an increased risk for severe coronary artery disease. Schwertner fails to teach that this method can also be used to determine the risk of systemic lupus erythematosus in an individual.

Manzi et al teach that patients with systemic lupus erythematosus are at an increased risk of developing cardiovascular disease, and thus coronary artery disease. See the abstract in Manzi et al. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the method taught by Schwertner involving the measurement of total bilirubin levels in serum samples for the evaluation of the risk of developing systemic lupus erythematosus in an individual since Manzi et al teach that people with systemic lupus erythematosus often have or develop coronary artery disease, and Schwertner teaches that coronary heart disease can be predicted by measuring low serum total bilirubin levels as compared to normal individuals. Therefore, one of ordinary skill in the art would expect that systemic lupus erythematosus would also be capable of being predicted by the measurement of

low serum total bilirubin levels since both coronary heart disease and systemic lupus erythematosus often occur simultaneously in an individual.

6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwertner (US Patent no. 5,380,667) in view of Jones et al. For a teaching of Schwertner, see previous paragraphs in this Office action. Schwertner fails to teach that the method involving measuring serum bilirubin levels can also be used to determine the risk of psoriatic arthritis in an individual.

Jones et al teach that the lipid profile in individuals with psoriatic arthritis closely matches the lipid atherogenic profile of individuals having cardiovascular disease or coronary artery disease. Therefore, individuals having psoriatic arthritis are at an increased risk for developing coronary artery disease. See the abstract in Jones et al. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the method taught by Schwertner involving the measurement of total bilirubin levels in serum samples for the evaluation of the risk of developing psoriatic arthritis in an individual since Jones et al teach that people with psoriatic arthritis often have or develop coronary artery disease, and Schwertner teaches that coronary heart disease can be predicted by measuring low serum total bilirubin levels as compared to normal individuals. Therefore, one of ordinary skill in the art would expect that psoriatic arthritis would also be capable of being predicted by the measurement of low serum total bilirubin levels since both coronary heart disease and psoriatic arthritis often occur simultaneously in an individual.

7. Claims 2 and 4 are allowable over the prior art of record since none of the prior art of record teaches or fairly suggests a method for characterizing the risk of systemic lupus erythematosus or psoriatic arthritis in an individual which comprises the steps of correlating an

Art Unit: 1743

individual's level of serum total bilirubin to a risk of systemic lupus erythematosus or psoriatic arthritis, wherein an obtained level of serum total bilirubin below the threshold levels recited in instant claims 2 or 4 indicates that the individual is at an increased risk for systemic lupus erythematosus or psoriatic arthritis.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Schwertner et al (US Patent no. 6,720,189), which corresponds to the parent application of this instant application.

Art Unit: 1743

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

August 23, 2004

Maureen M. Wallenhorst
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PRIMARY EXAMINER
GROUP 1200 1700